Draft Proposal to
Establish a 24-hour Standard for PM2.5

Review of the
California Ambient Air Quality Standards
For Particulate Matter and Sulfates

Report to the Air Quality Advisory Committee

Public Review Draft

March 12, 2002

California Environmental Protection Agency

Air Resources Board
and
Office of Environmental Health Hazard Assessment

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California Environmental Protection Agency

Winston Hickox, Secretary

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Draft Proposal to Establish a 24-hour standard for PM2.5

Background

In the initial Report to the Air Quality Advisory Committee (November 30, 2001), Air Resources Board (ARB) and Office of Environmental Health Hazard Assessment (OEHHA) staff did not propose a specific 24-hour standard for PM2.5. The Committee, however, unanimously recommended that staff develop such a standard, and suggested several possible approaches. Responding to the Committee's concerns and suggestions, OEHHA staff members have formulated the following recommendation, in consultation with staff at the ARB.

As reviewed in prior sections, the epidemiological literature suggests the existence of impacts on both morbidity and mortality related to fluctuations in ambient PM2.5 on a daily basis. Morbidity outcomes associated with changes in 24-hour concentrations in PM2.5 include admissions to hospitals for respiratory and cardiac diseases (see sections 7.5.1 and 7.5.2). There is also a growing literature suggesting potential mechanistic linkages between ambient PM2.5 and exacerbations of cardiovascular disease that could result in hospitalization or death (see section 7.8). These include associations with serious cardiac arrhythmias, myocardial infarctions, and decreased heart rate variability (Peters et al., 2000; 2001, Liao et al., 1999; Gold et al., 2000; Pope et al. 1999). As noted in prior sections, the entire spectrum of adverse health outcomes associated with ambient PM2.5, including exacerbations of asthma, emergency room visits, hospitalizations, as well as mortality, occurs within the same general concentration range and also seems to be best described by a linear, non-threshold model. Such a model implies that the level(s) at which adverse effects begin to occur cannot be identified and that there are no abrupt changes in the slope of the dose-response relationship to delineate a "bright line" or threshold.

Consistent observations of health effects associated with low ambient concentrations of fine particles, however, indicate that a short-term PM2.5 standard is required to protect public health. Moreover, while state-wide attainment of the proposed annual PM2.5 standard will result in a reduction of PM2.5 peak concentrations, some areas will be able to attain the annual standard and still experience periods during which 24-hour PM2.5 concentrations associated with increased morbidity and mortality can occur (e.g., during winter inversions accompanied by widespread residential wood combustion). This phenomenon also evidences the need for a short-term standard.

Development of a short-term standard for PM2.5, however, encompasses difficulties similar to those encountered with respect to the 24-hour standard for PM10, largely because the exposure-response relationships examined appear to be linear without clear evidence of a threshold. The linear, nonthreshold model carries implications for the determination of an "adequate margin of safety" specified in the language of the Children's Environmental Health Protection Act.

In order to address the lack of a "bright line" in the exposure-response curve, OEHHA staff members propose to reduce the entire distribution of fine particles below reported the levels of distributions consistently associated with adverse health effects. The underlying principle is to reduce not only the mean concentration (represented by the annual average), but specifically the upper tail of the distribution, described by the 98th percentile of the distributions of published studies. In so doing, OEHHA has relied primarily on studies relating fine particle concentrations with daily mortality, the most serious irreversible health impact. As noted above and in section 7.5, associations of PM2.5 with morbidity have been observed to occur within the same concentration range as those linked with increased daily mortality. We have therefore assumed that a standard intended to protect against the occurrence of mortality will also protect against these other important health outcomes.

Methodological Approaches

In developing this recommendation, OEHHA staff followed several approaches. Specifically, we have: (1) used statistical methods to examine the shape of the exposure-response relationships using two California datasets, and compared the results with those reported for other non-California datasets; (2) tabulated the results of all time-series studies published in English, for which direct PM2.5 monitoring data were available, that have explored associations between low levels of ambient PM2.5 and daily mortality; and (3) examined, with technical assistance from ARB staff, the upper tail of the PM2.5 distribution in California consistent with an annual average of 12 $\mu g/m^3$, based on data collected throughout California in 1999 and 2000. Based on the results of these analyses, OEHHA recommends that the 24-hour PM2.5 standard be established at a level of 25 $\mu g/m^3$, not to be exceeded. The adoption of the accompanying recommendation for an annual PM2.5 standard of 12 $\mu g/m^3$ is an integral component of this proposal. Attainment of the recommended annual standard will help shift the entire PM2.5 distribution to the left, and will influence peak concentrations, as well. However, in itself, the annual average will not fully address the issue of brief (i.e., one to several days) increases in PM2.5 levels. Thus, the 24-hour standard is intended to protect Californians against significant short-term elevations of PM2.5.

1. Statistical approaches

With the objective of further examining the validity of the linear model between mortality and PM2.5, staff from OEHHA and the Bay Area Air Quality Management District (BAAQMD) undertook a variety of detailed analyses of data from the two published California studies involving 24-hour measurements of PM2.5 and daily mortality counts (in Coachella Valley [Ostro et al., 2000] and Santa Clara County [Fairley, 1999]). The modeling techniques used for the exposure-response functions included piecewise linear regression (e.g., utilizing several "hockey-stick" models), locally weighted smoothing in generalized

1   additive models, trimming analysis (selectively deleting days with high PM2.5
2   values), and Bayesian models (comparing the likelihoods of various thresholds)
3   to explore the evidence for a nonlinear exposure-response at low PM2.5
4   concentrations. In general, within the concentration range of interest for PM2.5,
5   nonlinear models (and, in particular, models intended to identify possible
6   thresholds) offered no improvement over a linear, nonthreshold model in fitting
7   the data. These analyses, which are not presented in this document, are
8   consistent with results reported by almost all other researchers (except, e.g., for
9   Smith et al., 2000) using datasets from locations outside California. At least for
10   mortality, others have also found that a linear nonthreshold model best
11   characterizes the relationship between ambient PM2.5 and adverse health
12   outcomes (Pope, 2000 and section 7.3.5). A corollary of this observation is that,
13   in order to calculate a short-term PM2.5 standard, additional information (such as
14   the distributions of PM2.5 concentrations in published studies examining
15   exposure-response relationships) may be required.
16
17   *2. Distributions of PM2.5 in daily mortality studies.*
18
19   OEHHA staff obtained data from the authors of all recently published
20   studies examining ambient PM2.5 concentrations in relation to daily
21   nonaccidental mortality. Table 7.a provides information on the estimated
22   percentage change in daily mortality associated with a 10 μg/m^3 change in
23   PM2.5. All the point estimates of this relationship in Table 7.a are positive,
24   though not all are statistically significant. The upper tail of the PM2.5 distribution
25   in each of these investigations is indicated by the 98th percentile, which is
26   somewhat less subject to the factors determining the most extreme values.
27   Examination of the PM2.5 levels in Table 7.a indicates that, when the 98th
28   percentiles of the fine particle distributions are $\leq$32 μg/m^3, and the mean fine
29   particle concentrations are <13 μg/m^3, the results are characterized by greater
30   uncertainty, since the confidence intervals for the percent change in mortality
31   include zero. These were studies conducted in Portage (WI), Topeka (KS), and
32   in four Canadian cities (Calgary, Edmonton, Ottawa, and Winnipeg). One partial
33   exception to this observation is Vancouver, British Columbia, which had a 98th
34   percentile PM2.5 concentration of 30 μg/m^3, though the mean concentration was
35   13 μg/m^3. These results do not imply an absence of effects when peak PM2.5
36   concentrations are below 30 μg/m^3; rather, these estimates may be subject to
37   greater uncertainty potentially ascribable to several factors, including fewer
38   health impacts associated with exposure to lower concentrations, exposure
39   measurement error, confounding by co-pollutants or meteorological factors,
40   differences in the composition of particle mixtures, decreased statistical power,
41   and reduced variance in the PM2.5 values in studies with lower means. The last
42   explanation is unlikely, however, as we examined the coefficients of variation in
43   the studies with relatively low PM2.5 mean concentrations and found that they
44   were generally similar to those in the studies with higher mean levels. In
45   contrast, statistical power (i.e., the ability to detect statistically a real relationship
46   between two variables) is likely to be reduced at lower ambient pollutant

1 concentrations. Based on model simulations conducted by staff at the BAAQMD,
2 the increased uncertainty between lower-level PM2.5 concentrations and daily
3 mortality may be attributable in part to insufficient statistical power.
4
5   Published studies provide some guidance for an appropriate reduction in
6 the distribution of PM2.5. An annual PM2.5 standard of 12 μg/m^3 would
7 represent a level lower than the long-term means of all the studies in which
8 significant associations with changes in daily mortality have been identified (see
9 Table 7.a and section 7.3, above). Attainment of the annual average would, as
10 previously noted, result in an across-the-board reduction of PM2.5, including
11 peak concentrations. Setting a 24-hour standard level below 30 μg/m^3 would
12 shift the upper extreme of the PM2.5 distribution to a level lower than those
13 identified in the studies described above. Because the exposure-response
14 relationship is characterized by a linear, nonthreshold model, such a 24-hour
15 standard does not imply total elimination of health risks when this standard is
16 attained. However, reduction of peak PM2.5 concentrations below those
17 observed in studies reporting adverse effects represents a rational approach to
18 reduce the risk of short-term PM2.5-associated mortality and morbidity and to
19 position the entire distribution of PM2.5 below those for which there is current,
20 published evidence of health effects.
21
22 *3. Relationship of Recommended Annual PM2.5 Standards and 24-hour PM2.5*
23 *Concentrations in California*

24   As discussed in Chapter 6, the ARB uses the Expected Peak Day
25 Concentration (EPDC) to determine the "design value" for 24-hour standards.
26 The development of the EPDC uses a statistical model of the highest 20% of the
27 daily values from the previous three years, making it relatively robust with respect
28 to fluctuations in daily meteorological conditions. Specifically, the index will not
29 be unduly influenced by any single day, and exceptional events such as forest or
30 urban fires can be excluded. We used a modified version of this process to
31 examine the upper tail of the PM2.5 distribution (98th percentile) rather than the
32 most extreme values within California. With assistance from ARB staff, we
33 conducted an analysis to determine the relationship between the 98th percentile
34 of the PM2.5 distribution in California and the proposed annual average of 12
35 μg/m^3. This analysis identified the 98th percentile concentrations consistent with
36 an annual average of 12 μg/m^3, given recent statewide distributions of PM2.5.
37
38   Using data from 54 sites around the state, located principally in large
39 urban areas, a linear regression model was performed (linear models fit the data
40 better than non-linear models) relating the 98th percentile of the PM2.5
41 distribution to the annual average for the years 1999 and 2000 for each site. The
42 regression model generated an r^2 of 0.79 and indicated that statewide, the 98th
43 percentile for the distribution of PM2.5 associated with a 12 μg/m^3 annual
44 average is approximately 39 μg/m^3. For sites within the jurisdiction of the South
45 Coast Air Quality Management District, representing the most heavily populated
46 air basin in the state, the predicted 98th percentile concentration is approximately

1   37 μg/m^3, while the corresponding value for three other major air basins (the San
2   Francisco Bay Area, San Joaquin Valley, and Sacramento) is 45 μg/m^3, and that
3   for the South Central Coast is 33 μg/m^3.
4

5   This approach to identify ambient PM2.5 98th percentile concentrations
6   consistent with attainment of the proposed annual average indicates that, at least
7   in some of the heavily populated air basins, predicted concentrations of PM2.5
8   could fall within ranges previously reported to be associated with increased daily
9   mortality (Table 7.2) and morbidity. This modified EPDC exercise suggests the
10   need for a lower short-term standard to limit excursions of PM2.5 to protect
11   against increased risks of morbidity and mortality.
12

13   **Recommendation for 24-hour PM2.5 Standard**
14

15   Examining the evidence described above, OEHHA recommends that the
16   24-hour PM2.5 standard be 25 μg/m^3, not to be exceeded. The rationale for this
17   recommendation is as follows:
18

19   (i) Multiple analyses of the exposure-response relationships between
20   PM2.5 and mortality indicate that the data can be fitted most parsimoniously with
21   linear, nonthreshold models. Given the apparent linearity of the exposure-
22   response relationships in the epidemiological data, it is difficult to determine at
23   what concentrations within the PM2.5 distributions in each study adverse health
24   effects begin. Intuitively, one would expect greater biological responses and
25   larger numbers of adverse events occurring at higher concentrations, everything
26   else being equal. Nonetheless, in a linear exposure-response relationship,
27   effects may be observed at lower levels as well. (Schwartz et al., 1996)
28

29   The importance of the linear, nonthreshold exposure-response
30   relationship cannot be overemphasized in light of legislation requiring that
31   ambient air quality standards be "established at levels that adequately protect the
32   health of the public, including infants and children, with an adequate margin of
33   safety." (California Health & Safety Code Section 39606(d)(2)) If a threshold in
34   the exposure-response curve cannot be identified, then specification of an
35   "adequate margin of safety" becomes challenging. The approach OEHHA staff
36   members have adopted in pursuit of this objective has therefore been to: (1)
37   identify indicators of the distribution of PM2.5 (specifically the means and 98th
38   percentiles) in epidemiological studies that demonstrate the relationship of
39   ambient fine particles with adverse health impacts, (2) recommend that the
40   distribution of PM2.5 in California be reduced below the levels of these
41   distributions, and (3) incorporate a margin of safety in the form of a standard "not
42   to be exceeded", which will assure that the extreme values of the PM2.5
43   distribution in California will be lower (and in general substantially lower) than the
44   98th percentiles of PM2.5 distributions in published studies.
45

1   (ii) Without placing a short-term limitation on PM2.5 concentrations, recent
2 experience in California indicates that even attainment of the recommended
3 annual standard of 12 μg/m^3 will allow for excursions well into the range in which
4 adverse effects, including mortality, have been identified in epidemiological
5 studies. Notably, the modified EPDC analysis undertaken by the ARB staff
6 indicates that for several large air basins, the estimated 98th percentile of the
7 PM2.5 distribution consistent with attainment of an annual standard of 12 μg/m^3
8 would be in excess of 40 μg/m^3. Thus, adoption of a 24-hour standard of 25
9 μg/m^3 would be intended to limit such excursions.
10
11   (iii) As with PM10, morbidity and mortality outcomes appear to occur
12 within the same PM2.5 concentration ranges (See Section 7.5). Therefore, we
13 have focused on mortality as the most serious adverse health outcome. Changes
14 in ambient air quality sufficient to protect against increases in mortality should, *a*
15 *fortiori*, protect against the occurrence of morbidity, too.
16
17   (iv) Among studies examining PM2.5 and mortality, the long-term mean
18 concentrations of those finding a significant association varied from 13 to 21
19 μg/m^3, while the 98th percentiles of the distributions ranged from 30 to 51 μg/m^3.
20 Shifting the entire PM2.5 distribution downwards and limiting short-term
21 excursions should reduce the likelihood of fine particle-associated mortality and
22 morbidity. Recommending an annual average of 12 μg/m^3 addresses the issue
23 of shifting the overall distribution downwards. By the same token, recommending
24 a 24-hour PM2.5 limit of 25 μg/m^3 would place the upper extreme of the
25 distribution lower than the 98th percentile of those identified in studies finding
26 significant associations with mortality, thereby incorporating a margin of safety.
27 More specifically, except for the study of Vancouver (Burnett et al., 2000), all
28 published investigations of PM2.5 and mortality in which statistically significant
29 effects were detected had 98th percentile PM2.5 concentrations of 32 μg/m^3 or
30 greater. Positioning the upper extreme of the PM2.5 distribution in California at
31 25 μg/m^3 effectively incorporates a margin of safety into this recommendation,
32 based on the best available scientific evidence.

Table 7.a: Distributions and Associations of 24-hour PM2.5 with Daily Mortality in U.S. and Canadian Cities with Long-term Mean PM2.5 Concentrations < 25 μg/m³, Sorted by Reported 98 percentile Concentrations*

City	Study Period	Reference	Mean (μg/m³)	98th percentile	% Increase (95% CI) per 10μg/m³
Edmonton	1986-1996	Burnett et al., 2000	10	28	2.18(-1.74, 6.10)
Calgary	1986-1996	Burnett et al., 2000	10	29	0.63(-3.58, 4.84)
Winnipeg	1986-1996	Burnett et al., 2000	10	29	0.38(-3.15, 3.91)
Vancouver	1986-1996	Burnett et al., 2000	13	30	2.56(0.23, 4.89)
Topeka, KS	1979-1988	Schwartz et al., 1996	12	31	0.80(-0.20, 3.60)
Phoenix, AZ	1995-1997	Mar et al., 2000	13	32	2.22(0.00, 5.56)
Portage, WI	1979-1987	Schwartz et al., 1996	11	34	1.20(-0.30, 2.80)
Ottawa	1986-1996	Burnett et al., 2000	12	35	2.45(-0.53, 5.43)
Coachella Valley, CA	1995-1998	Ostro et al., 2000	17	38	4.44(0.00, 8.89)
Toronto	1986-1996	Burnett et al., 2000	15	41	0.91(-0.05, 1.87)
Boston, MA	1979-1986	Schwartz et al., 1996	16	42	2.20(1.50, 2.90)
Windsor	1986-1996	Burnett et al., 2000	18	43	5.20(2.24, 8.16)
Montreal	1984-1993	Goldberg et al., 2001	18	43	1.93(1.16, 2.71)
Kingston	1980-1987	Schwartz et al., 1996	21	44	1.40(0.20, 2.60)
St. Louis, MO	1979-1987	Schwartz et al., 1996	19	46	1.10(0.40, 1.70)
Santa Clara, CA	1990-1996	Fairley, 1999	13	51	3.18(0.00, 6.10)
Montreal	1986-1996	Burnett et al., 2000	15	51	1.23(0.11, 2.35)
Detroit, MI	1992-1994	Lippmann et al., 2000	18	55	1.24(-0.26, 2.83)

*Some data in Table 7.a, particularly most of the 98th percentile values, were obtained directly from the authors of the published reports.

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